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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,917	10/04/2004	Peter Muhlradt	03100215AA	4470

30743 7590 04/22/2010

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
04/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,917	MUHLRADT ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on 1-27-2010 is acknowledged. Claim 4 has been amended. Claims 1-5 and 12-16 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claim 4 for reciting improper Markush language is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1, 2, 4-5 and 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 9 of U.S. Patent No. 6,573,242 is maintained for reasons of record Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to vaccination methods utilizing the same peptide adjuvants.

Applicant argues:

1. The Muehlradt reference does not discuss mucosal delivery as required by the instant claims.
2. Example 1 of the specification demonstrated that MALP-2 had little or no potential as a mucosal adjuvant.
3. Example 2 of the specification demonstrated that increasing doses of MALP-2 led to the abolition of the adjuvant effect which would make it impossible to discern the adjuvant effect at standard concentrations used for other lipopeptides.
4. There are no adjuvants approved for the intranasal immunization of human patients.
5. Some of the experiments detailed in the present application could easily lead one of ordinary skill away from the use of MALP-2 as a mucosal adjuvant.
6. As pointed out in the declaration of Muehlradt, the effectiveness of a known adjuvant in a new experimental setting cannot be foreseen, hence, any reasoning that mucosal adjuvants are known in the art and it would be obvious to try MALP-2 as a mucosal adjuvant is faulty.
7. Claims of similar scope to the instant application and stemming from the same international application have issued in other parts of the world.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1-3 and 6, Applicant is reminded that the disclosures of the specification are not germane as the skilled artisan would not have had access to it prior to the filing of the instant application. However, the examples set forth in the specification, buttress the Examiner's position with regard to the methodologies employed by the skilled artisan. Example 2, clearly demonstrates that the skilled artisan would test the efficacy of a given adjuvant using multiple routes of administration and dosages. The KSR decision sets forth "if a technique has been used to improve one device, and a person of skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill". Given that Muehlradt demonstrates MALP-2 is an effective adjuvant and the various routes of administering adjuvants are well established in the art, the mucosal administration of MALP-2 is well within the capabilities of one of ordinary skill in the art. Hence, the requirements of obviousness under the KSR decision are met.

With regard to Point 4, the approval of a given compound for use in humans is the purview of the Food and Drug Administration. Moreover, the instant claims are not limited to the intranasal administration in humans. Finally, regardless of whether there are any FDA approved mucosal adjuvants for use in humans, the art is filled with examples of mucosal adjuvants that can be/are administered intranasally.

With regard to Point 5, there is no data presented in the cited references that would dissuade the skilled artisan for testing MALP-2 for efficacy as a mucosal adjuvant.

With regard to Point 7, Applicant is reminded that each application is examined in light of the statutes of the United States. Conclusions reached by other bodies have no bearing on said examination as they are not applying the same statutes.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-5 and 12-16 under 35 U.S.C. 103(a) as being obvious over Muehlradt (U.S. Patent 6,573,242) is maintained for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant argues:

1. The Muehlradt reference does not discuss mucosal delivery as required by the instant claims.

2. Example 1 of the specification demonstrated that MALP-2 had little or no potential as a mucosal adjuvant.

3. Example 2 of the specification demonstrated that increasing doses of MALP-2 led to the abolition of the adjuvant effect which would make it impossible to discern the adjuvant effect at standard concentrations used for other lipopeptides.

4. There are no adjuvants approved for the intranasal immunization of human patients.

5. Some of the experiments detailed in the present application could easily lead one of ordinary skill away from the use of MALP-2 as a mucosal adjuvant.

6. As pointed out in the declaration of Muehlradt, the effectiveness of a known adjuvant in a new experimental setting cannot be foreseen, hence, any reasoning that mucosal adjuvants are known in the art and it would be obvious to try MALP-2 as a mucosal adjuvant is faulty.

7. Claims of similar scope to the instant application and stemming from the same international application have issued in other parts of the world.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1-3 and 6, Applicant is reminded that the disclosures of the specification are not germane as the skilled artisan would not have had access to it prior to the filing of the instant application. However, the examples set forth in the specification, buttress the Examiner's position with regard to the methodologies employed by the skilled artisan. Example 2, clearly demonstrates that the skilled artisan would test the efficacy of a given adjuvant using multiple routes of administration and dosages. The KSR decision sets forth "if a technique has been used to improve one device, and a person of skill in the art would recognize that it would improve similar

devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill". Given that Muehlradt demonstrates MALP-2 is an effective adjuvant and the various routes of administering adjuvants are well established in the art, the mucosal administration of MALP-2 is well within the capabilities of one of ordinary skill in the art. Hence, the requirements of obviousness under the KSR decision are met.

With regard to Point 4, the approval of a given compound for use in humans is the purview of the Food and Drug Administration. Moreover, the instant claims are not limited to the intranasal administration in humans. Finally, regardless of whether there are any FDA approved mucosal adjuvants for use in humans, the art is filled with examples of mucosal adjuvants that can be/are administered intranasally.

With regard to Point 5, there is no data presented in the cited references that would dissuade the skilled artisan for testing MALP-2 for efficacy as a mucosal adjuvant.

With regard to Point 7, Applicant is reminded that each application is examined in light of the statutes of the United States. Conclusions reached by other bodies have no bearing on said examination as they are not applying the same statutes.

The rejection of claims 1-5 and 12-16 under 35 U.S.C. 103(a) as being obvious over Muhlradt et al. (Journal of Experimental Medicine, 1997, Vol. 185 No. 11, pages 1951-1958 – IDS filed on 4-12-2005) is maintained for reasons of record.

It should be noted that Applicant did not traverse this rejection in his response.

As outlined previously, Muhlradt et al. disclose a macrophage stimulator lipopeptide from *Mycoplasma fermentans* (MALP-2) which is an S-(2, 3-bisacyloxypropyl) cysteine-peptide wherein the peptide has the sequence of SEQ ID NO:3 (see abstract). Muhlradt et al. further disclose that MALP-2 is one of the most potent natural macrophage stimulators besides endotoxins (see abstract).

Muhlradt et al. differs from the instant invention in that he doesn't explicitly disclose the use of MALP-2 as a mucosal adjuvant generally or the recited routes of administration specifically.

Given that Muhlradt discloses that MALP-2 is one of the most potent natural macrophage stimulators besides endotoxins and the fact that the use of endotoxins as mucosal adjuvants is well known in the art, yielding predictable results, it is obvious for the skilled artisan to use the MALP-2 of Muhlradt et al. as a mucosal adjuvant (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). Moreover, the specific routes of administration and the types of antigens, carriers etc. set forth in the instant claims were also known in the art and would be equally obvious to the skilled artisan.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
April 20, 2010